



Health Canada authorizes Novavax's Nuvaxovid COVID-19 vaccine

From: [Health Canada](#)

Statement

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Today, Health Canada authorized Novavax's [Nuvaxovid COVID-19 vaccine](#) for the prevention of COVID-19 in adults 18 years of age and older. This is the fifth COVID-19 vaccine authorized in Canada. After a thorough, independent review of the evidence, the Department has determined that this vaccine meets Canada's stringent safety, efficacy and quality requirements.

Nuvaxovid is a [protein-based vaccine](#) that is administered as a two-dose regimen of 5 mcg per dose, 21 days apart.

Based on the clinical trials overall, Nuvaxovid is 90% effective at preventing symptomatic COVID-19 and 100% effective at preventing severe disease.

While additional confirmatory data is needed, preliminary and exploratory data shows that Nuvaxovid does produce neutralizing antibodies against the Omicron variant. As a term and condition associated with the authorization, Novavax is required to provide data regarding protection against current and emerging variants of concern as soon as it is available.

Health Canada has also placed terms and conditions on this authorization requiring the manufacturer to continue providing information to Health Canada on the safety, efficacy and quality of the vaccine to ensure its benefits continue to be demonstrated through market use.

Health Canada received an initial application for authorization from Novavax under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 on January 29, 2021. Novavax subsequently filed a submission under the amended *Food and Drug Regulations* on August 27, 2021, to support a permanent authorization.

In keeping with the Department's commitment to openness and transparency, Health Canada is publishing a number of documents related to its decision, including a high-level summary of the evidence it reviewed to support the authorization of the vaccine. More detailed information will be available in the coming weeks, including a detailed scientific summary and the full clinical trial results that support the use of this vaccine.

Health Canada and the Public Health Agency of Canada will closely monitor the safety of this vaccine once it is on the market and will not hesitate to take action if any safety concerns are identified.

For detailed information on authorized vaccines and treatments in Canada, visit the COVID-19 vaccines and treatments portal.

Contacts

Media Relations

Health Canada

613-957-2983

media@hc-sc.gc.ca

COVID-19 public enquiries: 1-833-784-4397

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